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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/940,378   | 08/27/2001  | Gust H. Bardy        | 032580.0017.UTL     | 2603             |
| 28075  | 7590        | 03/23/2004           | EXAMINER            |                  |
| CROMPTON, SEAGER & TUFTE, LLC<br>1221 NICOLLET AVENUE<br>SUITE 800<br>MINNEAPOLIS, MN 55403-2420 |             |                      | DROESCH, KRISTEN L  |                  |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             | 3762                 |                     |                  |
| DATE MAILED: 03/23/2004  |             |                      |                     |                  |

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                  |              |
|------------------------------|------------------|--------------|
| <b>Office Action Summary</b> | Application No.  | Applicant(s) |
|                              | 09/940,378       | BARDY ET AL. |
|                              | Examiner         | Art Unit     |
|                              | Kristen L Drosch | 3762         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 2/6/04 (response, IDS).
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 105-123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 117-123 is/are allowed.
- 6) Claim(s) 105, 108, 110 and 116 is/are rejected.
- 7) Claim(s) 106-107, 109, 111-115 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 06 February 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 108 is objected to because of the following informalities: "implanted to the patient".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 105, 108, and 116 are rejected under 35 U.S.C. 102(b) as being anticipated by Causey, III (5,411,547).

Regarding claims 105, Causey III shows a method of treating an abnormal sinus rhythm comprising providing a pair of electrodes disposed internal to a patient and exclusive of the patient's heart; sensing an event in the patient's sinus rhythm; transferring energy from an energy source (battery) to an energy storage system (capacitor); and discharging energy from the energy storage system using the electrode pair (Col. 1, lines 36-39; Col. 3, lines 28-53).

With respect to claim 108, Causey III shows providing an implantable stimulus device (28) into the patient which houses the energy source and the energy storage system and which is coupled to a lead system including at least one electrode of the electrode pair (34, 36, 38,40).

With respect to claim 116, Causey III shows the step of providing a pair of electrodes includes providing a pair of electrodes outside a patient's vasculature (Fig. 4).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 110 is rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III (5,411,547) in view of Bardy (5,292,338). Causey III is as explained before. Causey fails to specifically point out that the defibrillator is implanted subcutaneously between the third rib and the twelfth rib of the patient, but only mentions that a known defibrillator is used. Attention is directed to Bardy which teaches a known defibrillator that is implanted in the left infraclavicular pectoral region. As seen in Fig. 2 of Sanchez, Zambrano (5,895,414) the clavicle (21) is located approximately at the same location or level as the third rib (23) in the pectoral region. Thus, if the known defibrillator Bardy is implanted in the left infraclavicular pectoral region, it is advanced below the third rib and above the twelfth rib. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to implant the defibrillator of Causey III subcutaneously between the third rib and the twelfth rib of the patient as is known for implanting known defibrillators.

***Allowable Subject Matter***

6. Claims 106-107, 109, and 111-115 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 117-123 are allowed.

Regarding claims 106-107, the prior art of record fails to teach or suggest a method including providing a pair of electrodes disposed internal to a patient and exclusive of the patient's heart, transferring energy from an energy source to an energy storage system, and discharging energy from the energy storage system using the electrode pair in combination with determining whether the patient has an abnormally slow heartbeat, and wherein the step of sensing an event in the patient's sinus rhythm provides information for determining whether the patient has an abnormally slow heartbeat.

With respect to claim 109, the prior art of record fails to teach or suggest a method including providing a pair of electrodes disposed internal to a patient and exclusive of the patient's heart, transferring energy from an energy source to an energy storage system, and discharging energy from the energy storage system using the electrode pair in combination with providing an implantable stimulus device including implanting the stimulus device along the left axillary line of the patient.

Regarding claim 111, the prior art of record fails to teach or suggest a method including providing a pair of electrodes disposed internal to a patient and exclusive of the patient's heart, transferring energy from an energy source to an energy storage system, and discharging energy from the energy storage system using the electrode pair in combination with providing an implantable stimulus device including implanting the stimulus device along the inframammary crease of the patient.

With respect to claim 112, the prior art of record fails to teach or suggest a method including providing a pair of electrodes disposed internal to a patient and exclusive of the patient's heart, transferring energy from an energy source to an energy storage system, and

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discharging energy from the energy storage system using the electrode pair in combination with providing an implantable stimulus device including implanting the stimulus device at approximately the level of the cardiac apex.

Regarding claims 113-115, the prior art of record fails to teach or suggest a method including providing a pair of electrodes disposed internal to a patient and exclusive of the patient's heart, transferring energy from an energy source to an energy storage system, and discharging energy from the energy storage system using the electrode pair in combination with at least one of the pair of electrodes being located on a housing for the stimulus device.

With respect to claims 117-123, the prior art of record fails to teach or suggest a method including providing a pair of electrodes exclusive of the patient's heart; providing an implantable stimulus device at a subcutaneous location which is connected to a lead system including at least one electrode of the electrode pair, and transferring energy from an energy source to an energy storage system, discharging energy from the energy storage system using the electrode pair in combination with determining whether the patient has an abnormally slow heartbeat by sensing events in the patient's sinus rhythm.

***Response to Arguments***

8. Applicant's arguments with respect to claims 105, 108, 110, and 116 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Drolesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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